

**Notice of Allowability**

Application No.

09/843,150

Examiner

Patrick S. Riggins

Applicant(s)

CHAMBON ET AL.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the After Final Amendment filed 10/28/05 and the supplemental amendment filed 11/17/05.
2. ☒ The allowed claim(s) is/are 1,6,8-13,18,20-24 and 53.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

### **EXAMINER'S AMENDMENT**

1. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 11/29/05, Alexey Saprigin requested an extension of time for 2 MONTH(S) and authorized the Director to charge Deposit Account No. 190741 the required fee of \$450 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

3. Authorization for this examiner's amendment was given in a telephone interview with Alexey Saprigin on 11/11/05 and 12/7/05. The application has been amended as follows:

#### **In the Specification:**

4. It is noted that the amendment to the specification in the Supplemental After Final amendment filed 11/17/05 has not been entered due to improper referencing of the paragraphs to be replaced. The changes attempted in those un-entered paragraphs have been incorporated in

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this Examiner's Amendment. The other portions of the 11/17/05 After Final Amendment, including the new sequence listing, have been entered

5. To correct a reference to an incorrect sequence identifier, on page 8, line 11, "SEQ ID NO. 1" has been replaced with --SEQ ID NO. 52--.

6. To maintain consistency among all descriptions of the figures, on page 26, line 3, "Figures 1A-1D" has been replaced with --Figures 1A-D--.

7. To correct a reference to an incorrect sequence identifier, on page 55, line 25, "SEQ ID NO. 52" has been replaced with --SEQ ID NO. 57--.

**In the Claims:**

8. Claim 17 has been canceled.

9. Claims 1, 6, 8-13, 18, 20-24, and 53 have been amended and these amended claims have been allowed. The newly amended claims appear below.

1) An isolated DNA molecule comprising a sequence A flanked by site specific recombinase targeting sequences (SSRTS) L1 and a sequence B flanked by site specific recombinase targeting sequences (SSRTS) L2, said SSRTS L1 and SSRTS L2 being unable to recombine with one another, wherein:

- i) sequences L1 are in an orientation opposite one another, wherein said sequences point towards each other or away from each other,
- ii) sequences L2 are in an orientation opposite to each other, wherein said sequences point towards each other or away from each other,
- iii) the order of the sequences in said isolated DNA molecule is 5'-L1-L2-sequence A-sequence B-L1-L2-3', and
- iv) at least one of sequence A or sequence B encodes a protein.

6) The isolated DNA molecule according of claim 1 wherein the same recombinase recognizes SSRTS L1 and SSRTS L2.

8) The isolated DNA molecule of claim 6 wherein the recombinase specific for the SSRTS is selected from the group consisting of Cre recombinase of bacteriophage P1, the FLP recombinase of *Saccharomyces cerevisiae*, the R recombinase of *Zygosaccharomyces rouxii* pSR1, the A recombinase of *Kluyveromyces drosophilarius* pKD1, the A recombinase of *Kluyveromyces waltii* pKW1, the integrase  $\lambda$  Int, the recombinase of the GIN recombination system of Mu phage, and bacterial  $\beta$  recombinase.

9) The isolated DNA molecule according to claim 8, wherein said recombinase is said Cre recombinase of bacteriophage P1.

10) The isolated DNA molecule according to claim 9, wherein each of said SSRTS L1 and SSRTS L2, specific for Cre recombinase is selected from the group consisting of Lox P1, Lox 66, Lox 71, Lox 511, Lox 512, Lox 514, and a mutated Lox P1 sequence, wherein said mutated Lox P1 sequence comprises at least one point mutation in the spacer sequence.

11) The isolated DNA molecule according to claim 10, wherein either SSRTS L1 comprises the Lox P1 sequence (SEQ ID NO: 52) and SSRTS L2 comprises the Lox 511 sequence (SEQ ID NO: 53) or SSRTS L1 comprises the Lox 511 sequence and SSRTS L2 comprises the Lox P1 sequence.

12) The isolated DNA molecule according to claim 8 wherein the recombinase is the FLP recombinase of *Saccharomyces cerevisiae*.

13) The isolated DNA molecule according to claim 12, wherein said SSRTS L1 and/or SSRTS L2 specific for said FLP recombinase are chosen from the group consisting of FRT-S and FRT-F3<sup>0.88</sup>.

18) The isolated DNA molecule according to claim 1, wherein sequences A and/or B encode at least one exon.

20) The isolated DNA molecule according to claim 1, wherein an IRES sequence is inserted 5', 3', or 5' and 3' to the at least one of sequence A or sequence B that encodes a protein.

21) The isolated DNA molecule according to claim 53, wherein said reporter protein is selected from the group consisting of an autofluorescence protein and an enzyme detectable histochemically.

22) The isolated DNA molecule of claim 21, wherein said autofluorescence protein is selected from the group consisting of the green fluorescent protein (GFP), the enhanced green fluorescent protein (EGFP), the red fluorescent protein (RFP), the blue fluorescent protein (BFP), and the yellow fluorescent protein (YFP).

23). The isolated DNA molecule according to claim 21 wherein said enzyme detectable histochemically is selected from the group consisting of  $\beta$ -galactosidase,  $\beta$ -glucuronidase, alkaline phosphatase, luciferase, alcohol dehydrogenase, and chloramphenicol-acetyl transferase.

24) A vector comprising the isolated DNA molecule according to claim 1.

53) The isolated DNA molecule according to claim 1, wherein said protein is selected from the group consisting of a reporter protein and a selection marker.

***Oath/Declaration***

10. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

11. Applicant is now required to submit a substitute declaration or oath to correct the deficiencies set forth in this communication. The substitute oath or declaration must be filed within the THREE MONTH shortened statutory period set for reply in the “Notice of Allowability” (PTO-37). Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136. Failure to timely file the substitute declaration (or oath) will result in **ABANDONMENT** of the application. The transmittal letter accompanying the declaration (or oath) should indicate the date of the “Notice of Allowance” (PTOL-85) and the application number in the upper right hand corner.

**REASONS FOR ALLOWANCE**

12. The following is an examiner’s statement of reasons for allowance: the prior art of record does not teach or suggest a DNA molecule that comprises the recited sequences in the order and orientation recited in the allowed claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

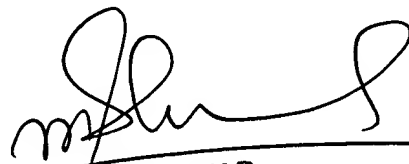
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick S. Riggins whose telephone number is (571) 272-6102. The examiner can normally be reached on M-F 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick Riggins, Ph.D.  
Examiner  
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**RAM R. SHUKLA, PH.D.**  
**SUPERVISORY PATENT EXAMINER**